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| 10/723,388 | 11/25/2003 | Pero Dimsoski | 5135 US | 7966 |

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MILA KASAN, PATENT DEPT.
APPLIED BIOSYSTEMS
850 LINCOLN CENTRE DRIVE
FOSTER CITY, CA 94404

| EXAMINER | |
|---|---|
| MUMMERT, STEPHANIE KANE | |
| **ART UNIT** | **PAPER NUMBER** |
| 1637 | |

DATE MAILED: 02/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/723,388 | DIMSOSKI ET AL. | |
| | Examiner | Art Unit | |
| | Stephanie K. Mummert | 1637 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *11/21/05*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *18-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-17 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 11/21/05

4)☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. 9/15/05

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

## DETAILED ACTION

Applicant's amendment filed on October 19, 2005 is acknowledged and has been entered. Claims 1, 5 and 16 have been amended. Claims 18-20 have been canceled. Claim 21 has been added. Claims 1-17 and 21 are pending.

Claims 1-17 and 21 are discussed in this Office action.

1. All of the amendments and arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons discussed below. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**This action is made FINAL.**

### *Information Disclosure Statement*

2. The information disclosure statement (IDS) submitted on November 21, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### *Previous Rejections*

The corrected inventorship included on the declaration filed on September 2, 2004 is noted. No further correction is required. The objection to the specification because it contains an embedded hyperlink and/or other form of browser-executable code is withdrawn in view of

Applicant's amendment to the specificiation. The claim rejection under 35 U.S.C. 102 directed to claims 18-19 as being anticipated by Tully is withdrawn in view of Applicant's cancellation of these claims. Upon reconsideration, the rejection of claim 12 under 35 U.S.C. 103 as being unpatentable over Soper in view of O'Neill is withdrawn as not applicable to the claim. The claim rejection under 35 USC 103 directed to claims 18-20 as being unpatentable over Tully in view of Yeung is withdrawn in view of Applicant's cancellation of these claims.

### *Claim Interpretation*

The term 'mobility modifier' is being given the broadest reasonable interpretation in light of the specification. In the specification, the term is defined that it 'refers to at least one polymer chain that when added to at least one reaction component that affects the mobility of the element to which it is bound'. The examiner reads that definition broadly to include any type of polymer, including polynucleotides, polypeptides, or synthetic polymers, for example.

### *Claim Rejections - 35 USC § 103*

Claims 1-11 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caskey (US Patent 5,364,759; November 1994) in view of Butler et al. (From IDS, Citation 18; 2003, J. Forensic Sci, volume 48(5), pages 1-11). Caskey teaches a method of DNA typing for the detection of short tandem repeat polymorphisms. Caskey teaches all of the limitations of claims 1-5, 8-11 and 16-17, as follows:

With regards to claims 1 and 16, Caskey teaches a method for isolating a labeled single-stranded target polynucleotide, comprising the steps:

1) forming a PCR reaction mixture comprising the following components and steps:

a. polynucleotide region of interest (Figure 1, see also column 3, lines 33-51),

b. a first primer specific for the region of interest, wherein the first primer has a label (column 3, lines 52-59) and a mobility modifier (column 10, lines 47-48, where a linker of DNA, which is being interpreted to be a mobility modifier, is attached to one of the primers),

c. a second primer specific for the region of interest, wherein the second primer comprises an affinity moiety (column 10, lines 54-55 where one primer is biotinylated), thereby forming a reaction mixture,

2) amplifying the region of interest (column 10, lines 43-59),

3) contacting the reaction mixture with a binding moiety specific for the affinity moiety,

4) binding the double stranded amplification product to the binding moiety (column 10, lines 56-57),

5) removing the unbound unincorporated reaction components, and

6) releasing the labeled single-stranded target polynucleotide that was formed in step (1) by denaturation (column 10, lines 63-67). Each step of this method is also detailed in Figure 1.

With regards to Claims 2, Caskey teaches the limitations of the method of Claim 1 (as described above) wherein the mobility modifier is polynucleotide linker molecule (Figure 1, see also, column 10, lines 47-48, where a linker of DNA is attached to one of the primers).

7. With regards to Claim 3, Caskey teaches the limitations of the method of Claim 1 (as described above) wherein the binding moiety is streptavidin (column 10, lines 56-57, see also Figure 2).

8. With regards to Claim 4, Caskey teaches the limitations of the method of Claim 1 (as described above) wherein the affinity moiety is biotin (column 10, lines 56-57, see also Figure 2).

With regards to Claims 5 and 17, Caskey teaches the limitations of the method of Claim 1 wherein the PCR mixture further comprises a plurality of primer sets (Table 6, where a representative list of the multiple STRs analyzed are listed), each primer set comprising a first and second primer flanking a different region of interest (Table 6, where a representative list of the multiple STRs analyzed are listed), wherein the first primer of each primer set further comprises the label (column 3, lines 52-55) and the mobility modifier (column 10, lines 47-48, where a linker of DNA is attached to one of the primers), and wherein the second primer further comprises the affinity moiety (column 10, lines 54-55 where one primer is biotinylated).

With regards to claims 8-11, Caskey teaches the amplification of regions of interest that comprise polymorphic microsatellites (column 3, lines 3-5) and further teaches that these polymorphic microsatellites can further comprise dinucleotide, trinucleotide, and tetranucleotide repeats (column 3, lines 34-51, where a short table describes the possible types of repeats).

Caskey is silent with regards to the limitations of Claims 6 and 7. Butler teaches development of reduced size STR amplicons as tools for the analysis of degraded DNA obtained from forensic samples. Butler teaches that DNA that is exposed to the elements can lead to degradation 'due to bacterial, biochemical or oxidative processes.' (p. 1, column 1, lines 5-8)

21. With regards to Claim 6, Butler teaches the polynucleotide region of interest is derived from a sample that further comprises degraded DNA (Abstract, lines 3-6, see also, p. 9, column 1, lines 19-28 and Figure 6, where aged bloodstains were studied).

With regards to Claim 7, Butler teaches the degraded DNA is reduced in size to between about 60 and 240 nucleotides (Table 1, where the markers are designed to prevent 'drop out' of alleles due to degradation and the resulting product sizes are within the specified range).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the teachings of Butler to the teachings of Caskey. The addition of linker arms to the PCR primers allows the practitioner in the field of STR analysis to have greater control over PCR product size(s) and would lends itself to greater flexibility in multiplex analysis of STR alleles. The teachings of Butler allow for more sensitive and robust amplification of DNA that has been obtained from forensic samples and degraded due to age or to exposure to the elements.

One of ordinary skill in the art of analysis of STR analysis and forensic science would recognize the benefit of increased sensitivity, increased ability to multiplex samples, and the ability to amplify DNA that is obtained in a sub-obtimal condition. Successful amplification of degraded or fragmented DNA allows forensic scientists to analyze samples that would have potentially failed attempts to amplify the samples using standard techniques at the time the invention was made.

Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caskey in view of Cotticone et al. (US Patent 6,841,349). Caskey teaches all of the limitations of Claims 1 as detailed above. Caskey is silent with regards to the limitations of claims 13-15. Cotticone teaches methods for the reduction of stutter in the amplification of microsatellite repeats.

With regards to Claims 13-15, wherein the PCR mixture further comprises sorbitol (claim 13), betaine (claim 14) or sorbitol and betaine (claim 15) together, Coticone teaches the addition of sorbitol (column 1, lines 8-11, see also column 2, lines 20-23), betaine (column 1, lines 8-11, see also column 2, lines 20-23), or sorbitol and betaine in combination (column 1, lines 8-11, see also column 2, lines 20-23) to reduce stutter in the amplification of microsatellite repeat alleles (column 1, lines 7-9).

Cotticone is silent with regards to the primer modifications associated with the method steps of Claim 1. Caskey teaches the amplification of short-tandem repeat polymorphisms using multi-step PCR amplification using unique linker arms and solid-phase DNA sequencing technology. Caskey teaches that this technique has increased sensitivity over conventional techniques and a significant reduction in the time required to obtain results.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the teachings of Caskey to the teachings of Cotticone. The addition of linker arms to the PCR primers allows the practitioner in the field of STR analysis to have greater control over PCR product size(s) and would lends itself to greater flexibility in multiplex analysis of STR alleles. The teachings of Cotticone add a useful improvement to the method of Caskey, through the reduction of stutter that is a common challenge in the analysis of microsatellite alleles and short-tandem repeat polymorphisms.

One of ordinary skill in the art of analysis of STR analysis and forensic science would recognize the benefit of increased sensitivity, increased ability to multiplex samples, reduction in stutter and a decrease in the time spent to obtain results.

*New Rejections*

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 12, the inclusion of the limitation that "at least one of the single stranded target polynucleotides results from amplification with a primer pair lacking a mobility modifier", as dependent from claim 5, which depends from claim 1 represents an improper and confusing dependency from claim 1. As currently stated, claim 1 requires, in step b, "a first primer specific for a region of interest, wherein the first primer has a label and a mobility modifier." It is unclear how the limitation, of a primer without the inclusion of a mobility modifier, could depend from a claim requiring this limitation.

***Claim Rejections - 35 USC § 103***

Claims 1-5, 8-11, 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caskey (US Patent 5,364,759; November 1994). Caskey teaches a method of DNA typing for the detection of short tandem repeat polymorphisms. Caskey teaches all of the limitations of claims 1-5,8-11 and 16-17, as follows:

5. With regards to claims 1 and 16, Caskey teaches a method for isolating a labeled single-stranded target polynucleotide, comprising the steps:

1) forming a PCR reaction mixture comprising the following components and steps:

a. polynucleotide region of interest (Figure 1, see also column 3, lines 33-51),

b. a first primer specific for the region of interest, wherein the first primer has a label (column 3, lines 52-59) and a mobility modifier (column 10, lines 47-48, where a linker of DNA, which is being interpreted to be a mobility modifier, is attached to one of the primers),

c. a second primer specific for the region of interest, wherein the second primer comprises an affinity moiety (column 10, lines 54-55 where one primer is biotinylated), thereby forming a reaction mixture,

2) amplifying the region of interest (column 10, lines 43-59),

3) contacting the reaction mixture with a binding moiety specific for the affinity moiety,

4) binding the double stranded amplification product to the binding moiety (column 10, lines 56-57),

5) removing the unbound unincorporated reaction components (col. 10, lines 63-67), and

6) releasing the labeled single-stranded target polynucleotide that was formed in step (1) by denaturation (column 10, lines 63-67). Each step of this method is also detailed in Figure 1.

With regards to Claims 2, Caskey teaches the limitations of the method of Claim 1 (as described above) wherein the mobility modifier is polynucleotide linker molecule (Figure 1, see also, column 10, lines 47-48, where a linker of DNA is attached to one of the primers).

7. With regards to Claim 3, Caskey teaches the limitations of the method of Claim 1 (as described above) wherein the binding moiety is streptavidin (column 10, lines 56-57, see also Figure 2).

8. With regards to Claim 4, Caskey teaches the limitations of the method of Claim 1 (as described above) wherein the affinity moiety is biotin (column 10, lines 56-57, see also Figure 2).

With regards to Claims 5 and 17, Caskey teaches the limitations of the method of Claim 1 wherein the PCR mixture further comprises a plurality of primer sets (Table 6, where a representative list of the multiple STRs analyzed are listed), each primer set comprising a first and second primer flanking a different region of interest (Table 6, where a representative list of the multiple STRs analyzed are listed), wherein the first primer of each primer set further comprises the label (column 3, lines 52-55) and the mobility modifier (column 10, lines 47-48, where a linker of DNA is attached to one of the primers), and wherein the second primer further comprises the affinity moiety (column 10, lines 54-55 where one primer is biotinylated).

With regards to claims 8-11, Caskey teaches the amplification of regions of interest that comprise polymorphic microsatellites (column 3, lines 3-5) and further teaches that these polymorphic microsatellites can further comprise dinucleotide, trinucleotide, and tetranucleotide repeats (column 3, lines 34-51, where a short table describes the possible types of repeats).

While Caskey teaches the inclusion of a label as a potential embodiment, Caskey does not explicitly teach the use of a label in addition to the polynucleotide linker in the amplification reaction disclosed at column 10. However, Caskey teaches an embodiment that includes "a differential label for each specific sequence is selected from the group consisting of fluorescers, radioisotopes, chemiluminescers, enzymes, stains and antibodies" (col. 3, lines 53-55). Furthermore, Caskey teaches, "the term 'differentially labeled indicates that each extension product can be distinguished from all others because it has a different label attached and/or is of

a different size and/or binds to a specifically labeled oligonucleotide." Based on the teachings of Caskey, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to incorporate a label into the amplification reaction recited in example 3, with a reasonable expectation for success.

5. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Caskey as applied to claims 1-5, 8-11, 16-17 above, and further in view of Grossman et al. (5,807,682; September 1998). Caskey teaches a method of DNA typing for the detection of short tandem repeat polymorphisms.

With regards to claim 21, Caskey teaches a method for isolating a plurality of different labeled single-stranded target polynucleotide, comprising the steps:

1) forming a polymerase chain reaction (PCR) mixture comprising:

a. plurality of polynucleotide regions of interest (Figure 1, see also column 3, lines 33-51),

b. a plurality of primer pairs, wherein each primer pair comprises a first primer specific for the region of interest, wherein the first primer has a label (column 3, lines 52-59) and a mobility modifier (column 10, lines 47-48, where a linker of DNA, which is being interpreted to be a mobility modifier, is attached to one of the primers), and a second primer specific for the region of interest, wherein the second primer comprises an affinity moiety (column 10, lines 54-55 where one primer is biotinylated), thereby forming a reaction mixture, wherein the first primer in each primer pair comprises a distinct label and mobility modifier (col. 3, lines 52-59, where differential labels for each specific sequence are used; also, col. 7, lines 4-12).

2) amplifying the region of interest, thereby producing a plurality of double stranded polynucleotide amplification products, wherein each product comprises a labeled single stranded target polynucleotide comprising the label and the mobility modifier, and a complementary affinity moiety strand (column 10, lines 43-59),

3) contacting the reaction mixture with a binding moiety specific for the affinity moiety,

4) binding the double stranded polynucleotide amplification product to the binding moiety (column 10, lines 56-57),

5) removing the unbound unincorporated reaction components (col. 10, lines 63-67), and

6) releasing the labeled single-stranded target polynucleotide that was formed in step (1) from the bound double stranded polynucleotide amplification products by denaturation (column 10, lines 63-67). Each step of this method is also detailed in Figure 1.

Caskey does not explicitly teach the amplification of a plurality of nucleic acid targets in a multiplexed format in the embodiment recited of the amplification method recited above. While Caskey does contemplate multiplex PCR amplification (col. 3, lines 20-28), Caskey does not explicitly teach the amplification of a plurality of nucleic acid targets in a multiplexed format in the example of the amplification method recited above. Grossman teaches the amplification of nucleic acids in a multiplex format, with the use of mobility modifiers to assist the resolution of a plurality of targets (col. 1, line 61- col. 2, line 28).

Regarding claim 21, Grossman teaches a plurality of probes (col. 4, lines 9-19; col. 16, lines 46-50, where at least one, but typically a plurality of regions for amplification) for use in ligase chain reaction (see Figure 12), wherein each primer pair comprises a first primer specific for the region of interest, wherein the first primer has a label (col. 4, lines 20-31; col. 16, lines

58-61, where the primer element carries at fluorescent reporter at it's 5' end; see Figure 12, element 100, 104, 106) and a mobility modifier (col. 4, lines 11-31; col. 16, lines 50-58, where the other probe/primer element includes at its 5' end, a selected-length polymer chain; see Figure 12, element 102).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to incorporate the multiplexed amplification taught by Grossman into the amplification technique taught by Caskey with a reasonable expectation for success. As noted by Grossman, "there is a growing need, e.g., in the field of genetic screening, for methods useful in detecting the presence or absence of each of a large number of sequences in a target polynucleotide. For example, as many as 150 different mutations have been associated with cystic fibrosis. In screening for genetic predisposition to this disease, it is optimal to test all of the possible different gene sequence mutations in the subject's genomic DNA... Ideally, one would like to test for the presence or absence of all of the possible mutation sites in a single assay" (col. 2, lines 36-46). Grossman establishes a need in the art for simultaneous amplification of multiple sites of mutation. Grossman further states, that "it is therefore desirable to provide a rapid, single-assay format for detecting the presence or absence of multiple selected sequences in a polynucleotide sample" (col. 2, lines 49-52). While the method taught by Grossman amplifies using ligase chain reaction, and the method taught by Caskey employs polymerase chain reaction, the motivation to incorporate a plurality of primers or to design a technique that incorporates multiplex amplification is applicable to both methods. Due to the benefit of improved cost in labor and reagents provided by the single-assay format taught by Grossman, one of ordinary skill in the art at the time the invention was made would have been

motivated to incorporate a multiplexed format to the amplification assay taught by Caskey with a reasonable expectation for success.

***Response to Arguments***

6. Applicant's arguments filed November 17, 2005 have been fully considered but they are not persuasive.

7. Applicant traverses the rejection of claims 1-5, 8-11, 16 and 17 under 35 U.S.C. 102(b) in view of Caskey, Applicant asserts that Caskey does not teach the step of amended claim 1 which recites "releasing labeled single stranded target polynucleotide from the bound double stranded polynucleotide amplification product by denaturation". Applicant refers to the portion of Caskey which states "..Fig 2B shows directed DNA sequencing of single stranded template following ***capture and strand separation of the biotinylated amplification products*** of λAE[AGAT]-2 with avidin coated magnetic beads" (col. 10, lines 63-67). Applicant goes on to note that the immobilized strand is sequenced in later steps of the method taught by Caskey and notes that Applicant's method does not "necessarily perform a reaction (sequencing, or otherwise) on the immobilized single stranded template" (p. 5-6 of arguments).

8. In response to Applicant's argument that Caskey does not teach the limitation of claim 1, the examiner notes the portion of the reference highlighted above, where an amplified product, formed with a mobility modified label is attached (see Figure 1) and where this double stranded PCR product is captured onto the magnetic bead, and the double stranded amplicon is denatured, which would therefore release or elute a single strand with a mobility modifier attached, which meets the limitations of the claim. The later steps highlighted by Applicant, which are directed

to sequencing the immobilized single stranded product are irrelevant to the step of Caskey that results in the elution of a single stranded product from the immobilized amplicon.

9. Applicant traverses the rejection of claims 1-11 and 16-17 under 35 U.S.C. 103(a) as being unpatentable over Caskey in view of Butler. Applicant asserts, for the reasons stated above, that Caskey does not teach all of the limitations of the claims.

10. In response to Applicant's argument that Caskey does not teach the limitations of claim 1, the examiner maintains the rejection for the reasons stated previously.

11. Applicant traverses the rejection of claims 22-23 under 35 U.S.C. 103(a) as being unpatentable over Caskey in view of Cotticone. Applicant asserts, for the reasons stated above, that Caskey does not teach all of the limitations of the claims.

12. In response to Applicant's argument that Caskey does not teach the limitations of claim 1, the examiner maintains the rejection for the reasons stated previously.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie K. Mummert whose telephone number is 571-272-8503. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0872. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephanie K. Mummert

Stephanie K Mummert
Examiner
Art Unit 1637

SKM

JEFFREY FREDMAN
PRIMARY EXAMINER
1/31/06